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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

03/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/421,106

Applicant(s)

BYRUM, JOSEPH R

Examiner

Young J Kim

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other

DETAILED ACTION

This Office Action is in response to the Amendment received on December 31, 2000.
Newly filed claim 16, drawn to elected Group I is acknowledged.

Election/Restrictions

This application contains claims 11-15, drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to this final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP 821.01.

Preliminary Remark

Office acknowledges the addition of claim 16, drawn to elected Group I and cancellation of claim 10.

Specification

The objection to the specification for making reference to an URL on the internet, on the Office Action mailed on September 12, 2000 is withdrawn in view of the Amendment received on December 12, 2000.

Claim Rejections - 35 USC § 112

The rejection of claims 1-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter in the Office Action mailed on September 12, 2000 is withdrawn in view of the Amendment received on December 12, 2000.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 1-9 (and newly submitted claim 16) under 35 U.S.C. for lacking patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility in the Office Action mailed on September 12, 2000 is maintained for the reasons of record.

Applicant's argument filed on December 12, 2000 have been fully considered but they are not found persuasive. Applicant argues that the Interim Guidelines ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts. Applicant describes a list of utilities the claimed nucleic acids could have, i.e., determining presence and/or identity of polymorphisms, measuring the level of mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetice map, probing for other molecules, etc.

The claimed nucleic acids do not have a specific utility. A nucleic acid, could certainly be used as a probe for detecting a condition, a primer for amplifying a region which would serve as an indication of something, determining the location of a corresponding DNA sequence on a physical or genetic map and thus determining the function of a gene, etc. The claimed nucleic acid lacks specific utility because the nucleic acids are not disclosed as being useful as a probe for detecting a specific clinical condition. Simply stating that a nucleic acid could be used as a probe, primer, or anything, does not constitute a specific utility because any piece of nucleic acid

would invariably hybridize to another piece of nucleic acid. The result of its hybridization, however, does not produce any real world application useful to one of ordinary skill in the art.

In response to Applicant's microscope analogy, Applicant is comparing the incomparable. A microscope, by virtue of its invention, has a real world application in magnifying microscopic objects that are known and exist to degrees in which human eyes are not capable of magnifying. The real world application of nucleic acid, however, are not amplifying anything or hybridizing to anything. It must, by its hybridization, or amplification (primer usage), etc., infer a useful information. It is that useful information which would give any nucleic acids a specific utility.

Further, in addressing the Applicant's golf club analogy, Applicant is in fact stating that a golf club has a specific utility, that is to hit a golf ball and not any object. This is equivalent to nucleic acids being useful as a probe for detecting a specific target sequence which could be an indication of specific condition. Simply stating that a nucleic acid has utility because it does something that's well recognized in the art (such as hybridizing to something) is not specific because one of ordinary skill in the art would not recognized what the nucleic acid is useful for. Expounding on the probe example, the probe's hybridization to its target nucleic acid would have to lead to a real world application that is useful to one of ordinary skill in the art for the utility to be specific.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

The rejection of claims 1-9 (and newly filed claim 16) under 35 U.S.C. 112, first paragraph because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above in the Office Action mailed on September 12, 2000 is maintained for the reasons of record.

Applicant's argument filed on December 12, 2000 have been fully considered but they are not persuasive for the reasons already set forth above.

The rejection of claims 1-9 (and newly filed claim 16) under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention in the Office Action mailed on September 12, 2000 is maintained for the reasons of record.

Applicant's argument filed on December 12, 2000 have been fully considered but are not found persuasive.

Applicant states that they "need not 'describe,' in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues" (pp. 10).

It is not apparent from the specification that claimed SEQ ID Numbers contain a complete open reading frame. Thus, barring evidence to the contrary, the nucleic acid comprising the claimed SEQ ID Numbers would read on undiscovered genes and nucleic acid sequences from other species, allelic variants, and so forth which are clearly not described by the

disclosure of the instant application. If the SEQ ID Numbers claimed by Applicant do contain complete open reading frames, and evidence is provided, the rejection will be withdrawn.

Claim Rejections - 35 USC § 102

The rejection of claims 1 and 4 under 35 U.S.C. 102(a) as being anticipated by Liu et al. and Imsande et al. in the Office Action mailed on September 12, 2000 is withdrawn in view of the Amendment received on December 12, 2000.

The rejection of claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by Larkins et al., (SEQ ID No. 2), Lindsay (SEQ ID No. 3), Shoemaker et al. (SEQ ID No. 4), Waterson (SEQ ID No. 6), Elder et al. (SEQ ID No. 9), and Nakamura (SEQ ID No. 10) in the Office Action mailed on September 12, 2000 is withdrawn after further consideration and in view of the Amendment received on December 12, 2000.

The rejection of claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by Laten et al. (SEQ ID No. 8) in the Office Action mailed on September 12, 2000 is maintained for the reasons of record.

Applicant's argument have been fully considered but are not found persuasive.

Applicant makes an argument that the nucleic acid disclosed by the cited artisan do not anticipate the invention as claimed because it does not meet the newly introduced limitation of "hybridizing, under conditions of 6.0x sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 x SSC at 50°C." (pp. 13). The USPTO does not have a facility to

conduct experimental procedures according to the set for hybridization/wash conditions and therefore, an assumption is made that Laten et al. do disclose a nucleic acid sequence that would hybridize under the set forth hybridization/wash conditions since it has 58.3% overall homology and 94.2% local similarity match to that of SEQ ID Number 8.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The

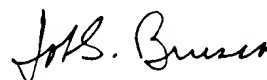
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faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)).

NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 308-0294. Please call the Examiner at (703) 308-9348 before the transmission to expedite delivery of the fax. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

02/27/01



JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER